



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Biomune Company
USDA Vet Biologics Establishment Number	368
Product Code	1431.56
True Name	Coccidiosis Vaccine, Live Oocysts
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Immucox 3 - No distributor specified
Date of Compilation Summary	June 28, 2017

**Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Eimeria acervulina</i>
<b>Study Purpose</b>	Pivotal efficacy against <i>Eimeria acervulina</i>
<b>Product Administration</b>	One dose administration by the gel droplet (oral) route
<b>Study Animals</b>	60 commercial chickens per treatment group vaccinated at day of age
<b>Challenge Description</b>	Homologous <i>Eimeria acervulina</i> administered at 28 days post vaccination
<b>Interval observed after challenge</b>	Daily observation for 6 days post challenge; Target tissues examined at day 6 post challenge
<b>Results</b>	<p>A chicken was considered affected by challenge if the lesion score was 2-4 (positive) and not affected by challenge if the lesion score was 0-1 (negative). Lesions were identified only in duodenum. No lesions were identified in the jejunum, ileum, or cecum.</p> <p>15/60 vaccinates and 41/60 controls had lesions from <i>Eimeria acervulina</i> challenge.</p> <p>Raw data shown on the following page.</p>
<b>USDA Approval Date</b>	January 13, 2016

Vaccinates			Controls		
Bird I.D.	Lesion Score	Result	Bird I.D.	Lesion Score	Results
122	0	Neg	123	4	Pos
124	0	Neg	125	1	Neg
127	0	Neg	126	3	Pos
129	0	Neg	128	2	Pos
130	2	Pos	132	2	Pos
134	0	Neg	136	3	Pos
135	4	Pos	137	3	Pos
139	3	Pos	138	3	Pos
143	0	Neg	140	3	Pos
146	3	Pos	141	0	Neg
149	0	Neg	147	0	Neg
154	0	Neg	150	3	Pos
155	3	Pos	156	0	Neg
157	0	Neg	160	3	Pos
158	0	Neg	161	2	Pos
159	0	Neg	165	3	Pos
162	3	Pos	166	2	Pos
163	0	Neg	167	1	Neg
164	0	Neg	169	4	Pos
170	0	Neg	180	3	Pos
171	0	Neg	182	0	Neg
174	3	Pos	184	1	Neg
176	0	Neg	185	1	Neg
178	0	Neg	190	3	Pos
179	0	Neg	192	0	Neg
181	3	Pos	193	2	Pos
186	0	Neg	194	3	Pos
188	4	Pos	196	3	Pos
189	0	Neg	206	1	Neg
191	0	Neg	207	3	Pos
197	0	Neg	209	2	Pos
198	3	Pos	210	0	Neg
199	0	Neg	211	0	Neg
201	0	Neg	213	3	Pos
202	0	Neg	216	0	Neg
203	0	Neg	217	2	Pos
205	0	Neg	221	1	Neg
208	0	Neg	224	3	Pos
214	0	Neg	226	0	Neg
215	0	Neg	229	3	Pos
218	3	Pos	231	3	Pos
219	0	Neg	232	2	Pos
220	0	Neg	233	2	Pos
222	2	Pos	234	4	Pos
223	1	Neg	237	3	Pos
225	0	Neg	241	1	Neg
227	0	Neg	242	3	Pos
228	0	Neg	243	3	Pos
230	3	Pos	244	4	Pos
235	2	Pos	247	0	Neg
236	0	Neg	248	2	Pos
238	1	Neg	249	3	Pos
239	1	Neg	250	0	Neg
240	0	Neg	253	2	Pos
245	0	Neg	254	2	Pos
246	4	Pos	255	3	Pos
251	1	Neg	256	0	Neg
252	1	Neg	259	3	Pos
257	0	Neg	260	4	Pos
258	1	Neg	261	2	Pos

Key:

0 No gross lesions

+1 Scattered, white plaque-like lesions containing developing oocysts are confined to the duodenum. These lesions are elongated with the longer axis transversely oriented on the intestinal walls like the rungs of a ladder. They may be seen from either the serosal or mucosal intestinal surfaces. They may range up to a maximum of 5 lesions per square centimeter.

+2 Lesions are much closer together, but not coalescent; lesions may extend as far posterior as 20 cm below the duodenum in 3-week-old birds. The intestinal walls show no thickening. Digestive tract contents are normal.

+3 Lesions are numerous enough to cause coalescence with reduction in lesion size and give the intestine a coated appearance. The intestinal wall is thickened and the contents are watery. Lesions may extend as far posterior as the yolk sac diverticulum.

+4 The mucosal wall is greyish with colonies completely coalescent. Congestion may be confined to small petechiae or, in extremely heavy infections, the entire mucosa may be bright red in color. The intestinal wall is very much thickened, and the intestine is filled with a creamy exudate which may bear large numbers of oocysts. Birds dying of coccidiosis are scored as +4.

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Eimeria maxima</i>
<b>Study Purpose</b>	Pivotal efficacy against <i>Eimeria maxima</i>
<b>Product Administration</b>	One dose administration by the gel droplet (oral) route
<b>Study Animals</b>	60 commercial chickens per treatment group vaccinated at day of age
<b>Challenge Description</b>	Homologous <i>Eimeria maxima</i> administered at 28 days post vaccination
<b>Interval observed after challenge</b>	Daily observation for 6 days post challenge; Target tissues examined at day 6 post challenge
<b>Results</b>	<p>A chicken was considered affected by challenge if the lesion score was 2-4 (positive) and not affected by challenge if the lesion score was 0-1 (negative). Lesions were identified only in jejunum. No lesions were identified in the duodenum, ileum, or cecum.</p> <p>4/60 vaccinates and 52/60 controls had lesions from <i>Eimeria maxima</i> challenge.</p> <p>Raw data shown on the following page.</p>
<b>USDA Approval Date</b>	January 13, 2016

Vaccinates			Controls		
Bird I.D.	Lesion Score	Result	Bird I.D.	Lesion Score	Results
5	0	Neg	1	1	Neg
7	0	Neg	2	3	Pos
9	0	Neg	3	3	Pos
10	1	Neg	11	0	Neg
19	0	Neg	13	2	Pos
21	1	Neg	14	3	Pos
22	0	Neg	15	2	Pos
23	0	Neg	16	2	Pos
27	1	Neg	17	2	Pos
28	0	Neg	18	3	Pos
29	0	Neg	20	2	Pos
30	0	Neg	24	2	Pos
31	0	Neg	25	1	Neg
33	0	Neg	26	3	Pos
34	1	Neg	36	2	Pos
35	0	Neg	37	3	Pos
38	0	Neg	39	1	Neg
41	0	Neg	42	3	Pos
44	0	Neg	45	0	Neg
46	0	Neg	50	3	Pos
47	0	Neg	51	3	Pos
48	0	Neg	52	2	Pos
49	1	Neg	56	2	Pos
53	2	Pos	62	2	Pos
55	0	Neg	68	2	Pos
57	0	Neg	69	3	Pos
58	0	Neg	73	3	Pos
59	0	Neg	77	2	Pos
60	1	Neg	79	2	Pos
63	2	Pos	80	3	Pos
64	0	Neg	84	3	Pos
65	1	Neg	85	3	Pos
67	0	Neg	87	2	Pos
71	0	Neg	90	2	Pos
72	1	Neg	92	2	Pos
74	1	Neg	93	3	Pos
76	0	Neg	94	3	Pos
78	0	Neg	95	3	Pos
81	0	Neg	97	2	Pos
82	0	Neg	98	3	Pos
88	0	Neg	101	3	Pos
89	0	Neg	103	1	Neg
91	2	Pos	104	2	Pos
96	0	Neg	109	2	Pos
100	0	Neg	110	3	Pos
105	0	Neg	112	2	Pos
106	2	Pos	119	2	Pos
107	1	Neg	121	1	Neg
108	0	Neg	123	3	Pos
111	0	Neg	124	2	Pos
113	0	Neg	127	2	Pos
114	1	Neg	128	3	Pos
115	1	Neg	129	2	Pos
116	0	Neg	130	0	Neg
118	1	Neg	132	3	Pos
122	0	Neg	134	2	Pos
125	0	Neg	135	3	Pos
126	0	Neg	136	2	Pos
133	1	Neg	138	2	Pos
139	0	Neg	140	2	Pos

Key:

0 No gross lesions.

+1 Small red petechiae may appear on the serosal side of the mid-intestine. There is no ballooning or thickening of the intestine, though small amounts of orange mucus may be present.

+2 Serosal surface may be speckled with numerous red petechiae; intestine may be filled with orange mucus; little or no ballooning of the intestine; thickening of the wall.

+3 Intestinal wall is ballooned and thickened. The mucosal surface is roughened; intestinal contents filled with pinpoint blood clots and mucus.

+4 The intestinal wall may be ballooned for most of its length; contains numerous blood clots and digested red blood cells giving a characteristic color and putrid odor; the wall is greatly thickened; dead birds are recorded with this score.

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Eimeria tenella</i>
<b>Study Purpose</b>	Pivotal efficacy against <i>Eimeria tenella</i>
<b>Product Administration</b>	One dose administration by the gel droplet (oral) route
<b>Study Animals</b>	60 commercial chickens per treatment group vaccinated at day of age
<b>Challenge Description</b>	Homologous <i>Eimeria tenella</i> administered at 28 days post vaccination
<b>Interval observed after challenge</b>	Daily observation for 6 days post challenge; Target tissues examined at day 6 post challenge
<b>Results</b>	<p>A chicken was considered affected by challenge if the lesion score was 2-4 (positive) and not affected by challenge if the lesion score was 0-1 (negative). Lesions were identified only in the cecum. No lesions were identified in the duodenum, jejunum, or ileum.</p> <p>5/60 vaccinates and 60/60 controls had lesions from <i>Eimeria tenella</i> challenge.</p> <p>Raw data shown on the following page.</p>
<b>USDA Approval Date</b>	January 13, 2016

Vaccinates			Controls		
Bird I.D.	Lesion Score	Result	Bird I.D.	Lesion Score	Results
863	0	Neg	861	3	Pos
864	1	Neg	862	4	Pos
866	0	Neg	865	3	Pos
873	1	Neg	867	4	Pos
875	1	Neg	868	3	Pos
882	1	Neg	871	4	Pos
884	0	Neg	872	3	Pos
896	0	Neg	874	3	Pos
899	3	Pos	877	3	Pos
902	0	Neg	879	3	Pos
903	1	Neg	880	3	Pos
905	0	Neg	881	3	Pos
906	0	Neg	885	3	Pos
907	1	Neg	886	3	Pos
908	1	Neg	887	3	Pos
911	0	Neg	888	3	Pos
913	1	Neg	889	3	Pos
914	1	Neg	890	2	Pos
916	0	Neg	892	2	Pos
917	0	Neg	893	4	Pos
918	0	Neg	894	3	Pos
919	1	Neg	898	4	Pos
921	0	Neg	900	2	Pos
924	2	Pos	909	4	Pos
925	1	Neg	910	3	Pos
926	2	Pos	912	2	Pos
927	0	Neg	915	3	Pos
928	1	Neg	920	3	Pos
933	0	Neg	922	3	Pos
934	0	Neg	923	4	Pos
936	1	Neg	931	3	Pos
938	0	Neg	932	4	Pos
939	1	Neg	935	4	Pos
941	1	Neg	937	3	Pos
943	0	Neg	940	3	Pos
944	0	Neg	942	3	Pos
945	1	Neg	948	4	Pos
946	0	Neg	954	3	Pos
947	3	Pos	956	3	Pos
949	1	Neg	959	2	Pos
950	1	Neg	960	4	Pos
953	0	Neg	962	3	Pos
957	1	Neg	963	4	Pos
958	1	Neg	966	3	Pos
961	0	Neg	967	4	Pos
964	0	Neg	968	2	Pos
965	1	Neg	971	2	Pos
969	1	Neg	973	3	Pos
970	2	Pos	974	4	Pos
976	0	Neg	975	4	Pos
980	0	Neg	977	2	Pos
984	1	Neg	978	3	Pos
986	1	Neg	981	3	Pos
987	1	Neg	982	4	Pos
988	0	Neg	983	4	Pos
990	0	Neg	985	4	Pos
991	1	Neg	994	3	Pos
992	1	Neg	995	3	Pos
993	0	Neg	996	3	Pos
997	0	Neg	998	3	Pos

**Key:**

0 No gross lesions.

+1 Very few scattered petechiae on the cecal wall; no thickening of the cecal walls; normal cecal contents present.

+2 Lesions more numerous with noticeable blood in the cecal contents; cecal wall is somewhat thickened; normal cecal contents present.

+3 Large amounts of blood or cecal cores present; cecal walls greatly thickened; little, if any, fecal contents in the ceca.

+4 Cecal wall greatly distended with blood or large caseous cores; fecal debris lacking or included in cores. Dead birds are scored as +4.



<b>Study Type</b>	Safety																																			
<b>Pertaining to</b>	ALL																																			
<b>Study Purpose</b>	To demonstrate safety under field conditions.																																			
<b>Product Administration</b>	Single dose, gel droplet administration																																			
<b>Study Animals</b>	Commercial chickens at day of age. Three independent study sites																																			
<b>Challenge Description</b>	NA																																			
<b>Interval observed after challenge</b>	Chickens were observed daily for 21 days post vaccination																																			
<b>Results</b>	<table> <tr> <th>Site</th><th>Treatment</th><th>Number of Chickens</th><th>Percent Mortality</th><th>Percent Condemnation</th></tr> <tr> <td rowspan="2">1</td><td>Vaccinate</td><td>13,500</td><td>2.0</td><td>Not available</td></tr> <tr> <td>Control</td><td>13,500</td><td>1.8</td><td>Not available</td></tr> <tr> <td rowspan="2">2</td><td>Vaccinate</td><td>17,700</td><td>1.1</td><td>Not available</td></tr> <tr> <td>Control</td><td>17,700</td><td>1.0</td><td>Not available</td></tr> <tr> <td rowspan="2">3</td><td>Vaccinate</td><td>17,300</td><td>1.5</td><td>Not available</td></tr> <tr> <td>Control</td><td>17,300</td><td>1.4</td><td>Not available</td></tr> </table> <p>No adverse reactions observed</p>				Site	Treatment	Number of Chickens	Percent Mortality	Percent Condemnation	1	Vaccinate	13,500	2.0	Not available	Control	13,500	1.8	Not available	2	Vaccinate	17,700	1.1	Not available	Control	17,700	1.0	Not available	3	Vaccinate	17,300	1.5	Not available	Control	17,300	1.4	Not available
Site	Treatment	Number of Chickens	Percent Mortality	Percent Condemnation																																
1	Vaccinate	13,500	2.0	Not available																																
	Control	13,500	1.8	Not available																																
2	Vaccinate	17,700	1.1	Not available																																
	Control	17,700	1.0	Not available																																
3	Vaccinate	17,300	1.5	Not available																																
	Control	17,300	1.4	Not available																																
<b>USDA Approval Date</b>	January 21, 2016																																			